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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,604	03/22/2001	Elliott S. Klein	P-AR 4528	4120

23601 7590 09/09/2003

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/814,604

Applicant(s)

KLEIN ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. - - - - -

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Formal Matters***

Claims 1-26 are pending and under consideration.

### ***Response to Arguments***

Applicant's arguments filed 3/31/2003 have been fully considered but they are persuasive in part, for the reasons set forth below.

The rejection of claims 1-26 under 35 U.S.C. 102(a) as being anticipated by Klein et al. (2000) has been withdrawn.

### ***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 11 and 18 are vague and indefinite in the recitation of the term "test complex". For example, claim 1(a) indicates that the test complex comprises a nuclear hormone receptor, a coactivator and a corepressor, then the steps further on measure the association of the coactivator or corepressor with the test complex. It is not clear whether the coactivator and corepressor are parts of the test complex, or if the test complex is really just the receptor dimer and the coreceptor and corepressor only associate with it, and thus the metes and bounds of the claims cannot be determined. Claims 3-10, 12-17, 19-26 are rejected insofar as they depend on the recitation of the term "test complex" in claims 1, 2, 11, 18.

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Claims 1, 2, 11 and 18 are vague and indefinite in the recitation of the term “activities”. This term is not clearly defined in the claims. The specification also does not clearly define the term, but it seems to include, *inter alia*, an indirect signaling pathway activated by the nuclear hormone receptor, and on other nuclear hormone receptor mediated pathways (page 9, lines 5-20), and also a decrease in interaction with corepressors and an increase in interaction with coactivators (page 14, lines 10-20). Thus, since the term “activities” includes effects on indirect pathways not directly associated with nuclear hormone receptor function, the skilled artisan would not be apprised of the metes and bounds of the functional limitation with regard to the activities which are dissociated. Claims 3-10, 12-17, 19-26 are rejected insofar as they depend on the recitation of the term “activities” in claims 1, 2, 11, 18

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-26 stand rejected under 35 U.S.C. 102(b) as being anticipated by DiRenzo et al. (1997), for reasons of record set forth in paper No. 10, 12/2/2002.

The rejection of record set forth that Dorenzo et al. describes allosteric interactions between RXR and two heterodimeric partners, retinoic acid receptors (RARs) and peroxisome proliferator-activated receptors (PPARs); RARs and PPARs prevent and permit activation by

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RXR-specific ligands, respectively (page 2166). DiRenzo et al. teaches a method of determining the effect of an agent (TTNPB) on the recruitment of corepressor (NCoR) and coactivator (SRC-1) on RAR and PPAR (page 2173, Figure 6). In this method both the coactivator and corepressor are measured. This anticipates claims 1-26.

Applicant argues that the RARalpha assays of DiRenzo do not anticipate the claimed invention because there is no RXR present to form a heterodimer. However, the claims only require that the assay be carried out under condition suitable for formation of a dimer. In this case, RARalpha can form a homodimer, thus meeting this limitation of the claims. The teaching of DiRenzo et al., specifically Figure 6B demonstrates that RARalpha can interact with both NCoR and SRC-1 simultaneously. Applicant further argues that the teaching of DiRenzo fails to identify an effective agent that dissociates nuclear hormone receptor activities. However, the claims are directed to methods of identification of effective agents which dissociate nuclear hormone receptor activities. The method as set forth in DiRenzo et al. is capable of identifying agents that dissociate nuclear hormone receptor activities, and it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over DiRenzo et al. (1997), for reasons of record set forth in paper No. 10, 12/2/2002.

The rejection of record set forth that DiRenzo et al. describes allosteric interactions between RXR and two heterodimeric partners, retinoic acid receptors (RARs) and peroxisome proliferator-activated receptors (PPARs); RARs and PPARs prevent and permit activation by RXR-specific ligands, respectively (page 2166). DiRenzo et al. teaches a method of determining the effect of an agent (TTNPB) on the recruitment of corepressor (NCoR) and coactivator (SRC-1) on RAR and PPAR (page 2173, Figure 6). In this method both the coactivator and corepressor are measured. DiRenzo et al. further discloses that it is possible that other members of the SRC-1 family of coactivators, such as TIF-2 are also coactivators for nuclear hormone

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receptors (page 2175 column 1, first paragraph). Therefore it would have been obvious to one of skill in the art at the time the invention was made to practice a method of method of determining the effect of an agent on the recruitment of corepressor and coactivator (wherein the coactivator is TIF-2/GRIP-1/NcoA-2) on RAR. The motivation is provided in DiRenzo et al. who teaches that arriving at an understanding of the mechanisms by which coactivators and corepressors function and characterizing their biological roles will be of great interest (page 2175, column 1, fourth paragraph).

Applicant argues that the teaching of DiRenzo fails to teach or suggest a method to identify an effective agent that dissociates nuclear hormone receptor activities or identification of such an effective agent by coactivator association combined with corepressor association. However, the claims are directed to methods of identification of effective agents that dissociate nuclear hormone receptor activities. The method as set forth in DiRenzo et al. is capable of identifying agents that dissociate nuclear hormone receptor activities, and it does not appear that the instant claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

### ***Conclusion***

No claim is allowed.

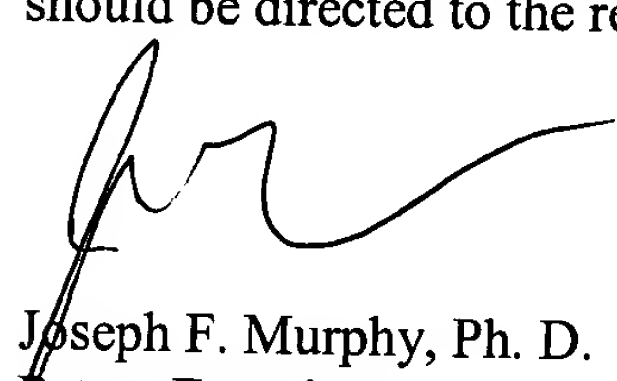
*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.


The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
September 3, 2003



YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
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